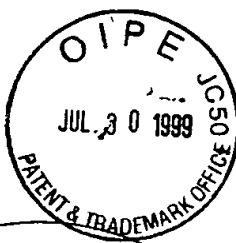


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37 C.F.R. §1.8

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Peter J. Manso

7/26/99  
Date

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Eugeno Cefali  
Serial No.: 08/962,027  
Filing Date: October 31, 1997  
Group Art Unit: 1615  
Examiner: Benston, Jr., W.  
Title: *Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia Having Unique CMAX, TMAX and AUC Biopharmaceutical Characteristics*

Box Non-Fee Amendment  
Assistant Commissioner for Patents  
Washington, D.C. 20231

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**RESPONSE TO OUTSTANDING OFFICE ACTION MAILED ON JANUARY 25, 1999**

This Response to the Outstanding Office Action mailed on January 25, 1999 in connection with the above-identified application for U.S. patent.

In the January 25th Office Action, the Examiner rejected previous claims 1-28 under 35 U.S.C. §103(a) as being unpatentable over Dennick. According to the examiner:

Claims [1-28] read on intermediate release Nicotinic Acid Formulations for oral administration and treating Hyperlipidemia. Dennick, teaches a Nicotinic Acid Formulation suitable for oral administration (COL. III, L. 17-20, 40-55), and in tablet form (COL. III, L. 57). It would have been obvious to one of ordinary skill in the art at the time of invention to use the teachings of Dennick, who teaches Nicotinic Acid for lowering serum cholesterol. The intended purpose is to provide intermediate release Nicotinic Acid formulations for oral administration for treating hyperlipidemia.

Applicant respectfully disagrees. Dennick simply discloses the use of Nicotinic Acid. Dennick does not teach whether the Nicotinic Acid is in an immediate release formulation, intermediate release formulation or sustained release formulation. In fact, Dennick is totally silent as to any formulation for the Nicotinic Acid discussed therein, or the time of administration thereof.

To the contrary, applicants have discovered an intermediate release Nicotinic Acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release Nicotinic Acid formulation to be discontinued. In addition, applicants have discovered that the intermediate release Nicotinic Acid formulation as claimed in Claims 1-28 have a unique nicotinuric acid C<sub>max</sub>, a unique nicotinuric acid T<sub>max</sub> and a unique AUC for nicotinuric acid, as claimed in Claims 1-28.

It is respectfully pointed out that Dennick is totally silent with respect to these parameters as claims in presently pending Claims 1-28.

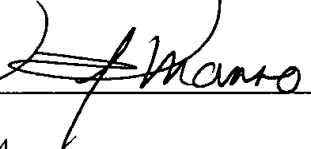
In view of the above, it is respectfully submitted that Dennick either alone or in any appropriate combination does not teach or suggest the intermediate release Nicotinic Acid formulations as claimed in Claims 1-28. It is further respectfully submitted that the secondary references do not cure the deficiencies of Dennick.

Thus, it is respectfully submitted that all presently pending Claims 1-28 are patentably distinct over the disclosures of record when a disclosures are considered either alone or in any appropriate combination. It is further respectfully submitted that all currently pending claims are in conformance with 35 U.S.C. §112. It is further respectfully submitted that the Dennick patent does not inherently produce the Nicotinuric Acid profiles, as claimed, and avoid treatment-limiting hepatotoxicity.

As a result of the foregoing, it is respectfully submitted that the present application and all pending Claims 1-28 are not in condition for allowance. Therefore, early passage of the above-referenced application for U.S. patent to issuance is earnestly solicited. Should the Examiner have any questions or require additional information or clarification, applicant requests that the Examiner contact the attorney of record herein, Peter J. Manso, at the phone numbers noted below.

Respectfully Submitted,

Date: July 26, 1999

  
Peter J. Manso  
Reg. No. 32,264

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